

IT tools infrastructure for use and exposure information

improved efficiency, transparency
and consistency

ENES 9

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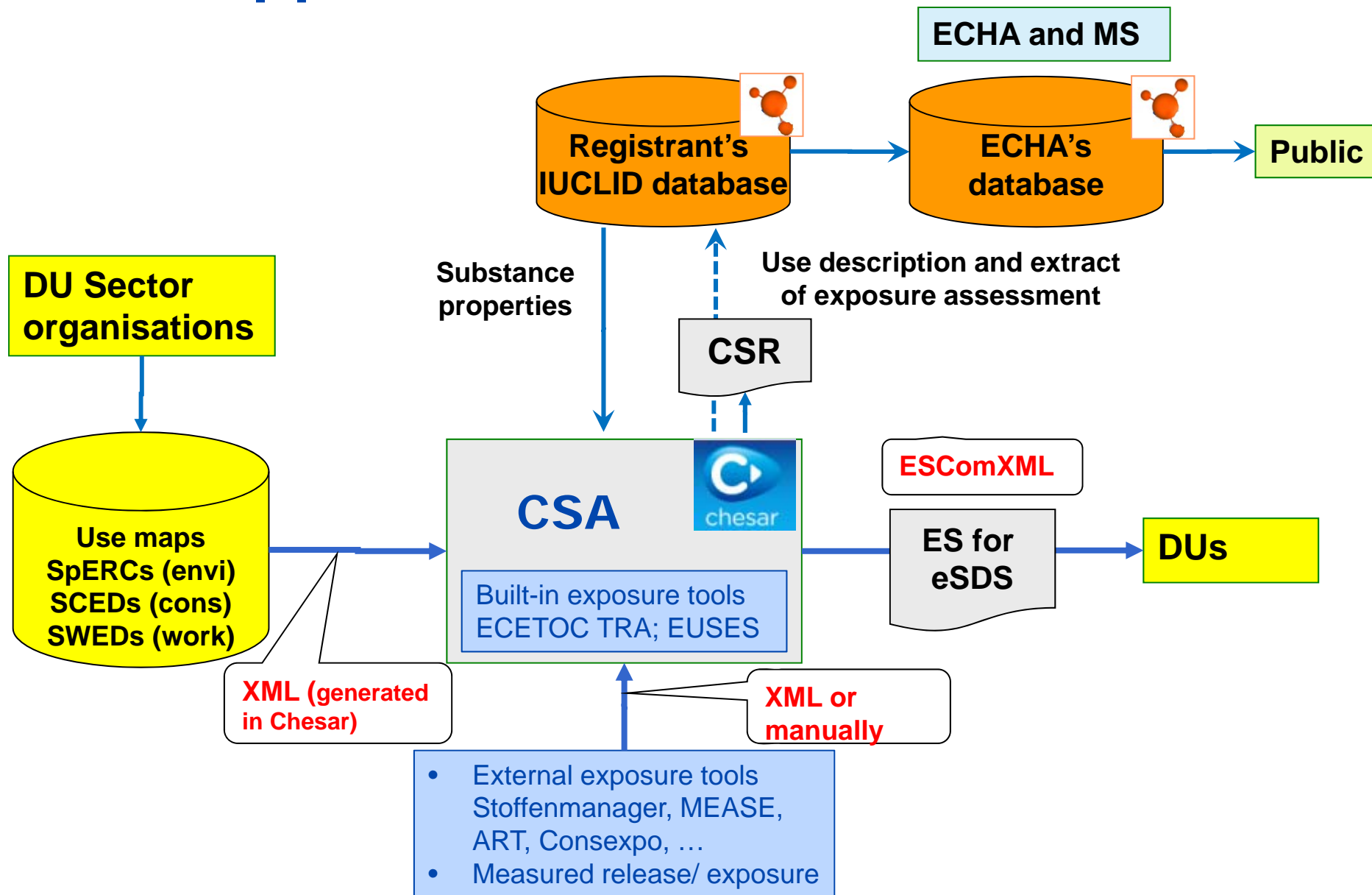
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Background

To meet the objectives of REACH, information is to be

- exchanged and further processed
 - within the supply chains
 - between industry and authorities
 - disseminated to the public
- IT support is crucial for efficient exchange, processing and maintenance

IT support to data flow



IUCLID 6



Use and exposure information in IUCLID 6 (1/2)

Use and exposure information is key to support priority setting by the authorities for further regulatory actions:

- give lower priority to those (potentially) hazardous substances which have
 - no use (or very low tonnage) in the scope of SEv, authorisation, CLH, restriction
 - no (or very low tonnage) in wide dispersive uses

Reminder: " Wide dispersive" means

- *widespread* (used at many sites, by many users) and
- *potential for release to environment and/or potential for human exposure*

Use and exposure information in IUCLID 6 (2/2)

- Provides (non-mandatory) fields for demonstrating that a substance is of low concern under REACH:
 - regulatory/registration status
 - low number of sites
 - high level of containment
- The information will have an impact on the rank only
 - if all uses are flagged like this or
 - if there is information on the tonnage per use
- For example: Main tonnage for uses without potential for release (e.g. use in contained system with strict control)

IUCIID 6 supports more transparent data organisation for “complex cases” (1)

If one substance needs multiple data-sets for the assessment:

- (group of) constituents behaving differently from each other
- Substance transforming during use or in the environment
 - Unintended transformation
 - Intended change of form or composition
 - The substance is meant to react for delivering its technical function
- Different compositions (or form) of the substance with different hazard profile

IUCLID 6 supports more transparent data organisation for “complex cases” (2)

“Assessment entity” in IUCLID 6 enables

- to group substance property data-sets for the assessment
- to clearly explain the assessment approach and to improve understandability of disseminated information
- opportunities for the assessor to make his case more transparent (non mandatory)

Improved sector use maps



From sector use maps to registrations

- Current excel template to be populated by sectors
- XML format foreseen in Chesar 3 (could be used by other CSA tool)
 - To support import of improved use maps generated by sectors by registrants
- Still to be further worked out:
 - How to best support selection of relevant uses by registrants?
- To be further reflected:
 - How to best make available all developed use maps to registrant?

Chesar 3



Scope of Chesar 3.0

- Ensure link to IUCLID 6
- Expand the scope to cases when several sets of substance properties play a role (assessment entity in IUCLID)
- Increase usability (efficient CSA), for example:
 - Editing conditions of use or qualitative risk characterisation for several contributing scenarios in one go
 - Automated generation of (qualitative) risk characterisation based on concentration limit for skin and eye local effects

Support foreseen

- Aim is to increase training efforts for new and existing users
- Training needs are being assessed (survey carried out in September)
- Support material
- Training to trainers to take place in 2016
- Specific support to sector associations for generating use maps/exposure assessment inputs elements so that they can be used in Chesar

Timeline

- **Chesar 3.0** released together with IUCLID 6 in Q2 2016
 - Chesar 2.3 data will be migrated to Chesar 3
- Release of **Chesar 3.1** in October 2016 (initial plan).
Completion of key features to prepare for registrations:
 - Complete integration of Roadmap products: **Use maps** and **SWED** for downstream sectors to prepare
 - Full export to IUCLID 6
 - Start enhancing user friendliness (in particular CSR preview)
 - Generation of ESComXML?

Next versions of Chesar (2/2)

- Preparation for **Chesar 3.2** (Q1/2017 ?)
 - Complete the improvements of the user friendliness
 - Complete assessment workflow for few “specific” cases.
 - Align with potential modifications in ECETOC TRA
 - Other based on feedback?
- After 3.2: progressive maintenance
 - Feedback from CSR/ES roadmap
 - Based on experience with complex cases.

Conclusion

- Significant investment made to build a tool infrastructure supporting efficient exchange and processing of information on use and exposure
- We are looking forward to industry taking the opportunity to generate and exchange good quality information in an efficient way.

Thank you!

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